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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/046,610	05/30/2001	Nobuhisa Hirai	Q64728	5530
7590 06/02/2004 SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, N.W. Washington, DC 20037			EXAMINER TRAN LIEN, THUY	
			ART UNIT 1761	PAPER NUMBER

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,610

Applicant(s)

HIRAI ET AL.

Examiner

Lien T Tran

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extension of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 19, 20, 23-25, 28-30 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19, 20, 23-25, 28-30 and 33-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/ISB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-15, 19-20,23-25,28,29,30,33,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jp 2000044878 in view Orthoefer.

Jp2000044878 discloses a coating agent which comprises a yeast cell wall fraction mainly comprising a microbial cell residue. The coating agent is used as coatings of foodstuff, pharmaceuticals, enzyme, microorganisms, flavoring agent etc... The coating agent has very low oxygen permeability, not stickiness and controls an elution initiation time. Applicant discloses on page 3 of the specification, the patent also teaches to incorporate a plasticizer in the coating material.

The Japanese patent does not disclose one member selected from a group consisting of viscous polysaccharides, oligosaccharide, sugar alcohol or the specific polysaccharide and oligosaccharide as claimed .

Orthoefer discloses plasticizers including sugar alcohol, polysaccharide, oligosaccharide such as raffinose. (See columns 3-4 which disclose all the materials which can be used as plasticizers)

The Japanese patent teaches to incorporate plasticizer in the coating agent. It would have been obvious to one skilled in the to use any known plasticizer such those disclosed by Orthoefer. While Orthoefer does not disclose the same sugar alcohol as claimed, he does teach the use of general sugar alcohol as a plasticizer. In absence of showing of unexpected result or criticality, it would have been obvious to use any known sugar alcohol and all the sugar alcohols claimed are well known in the art. As to the size, it would have been obvious to make the product in the size that is appropriate to the intended use. For example, if the coated powder is used in a liquid product, it would

have been obvious to make the product in small size so that it would dispersed readily in the liquid. However, if the coated powder is used into a solid food product or pharmaceuticals, the size can be bigger. One skilled in the art can readily determine the appropriate size through routine experimentation, depending on the intended use. It would also have been obvious to one skilled in the art to determine the coating ratio through routine experimentation to obtain a product which provides the most optimum intended function. For example, if the core agent is coated to enhance shelf stability by providing a barrier layer, it would have been obvious to have a thicker coating versus a core agent which is coated to control release time.

Claims 11 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jp2000044878 in view of Orthoefer as applied to claims 1-8 and 12-17 above, and further in view of Percel.

The Japanese patent does not disclosed coating the core under stirring or fluidized state.

Percel et al teach a process to coat core particles. The process comprises the steps of forming a fluid bed of the core particles and spraying into the bed in the form of a fine mist the coating agent. (See columns 3-4)

It would have been obvious to one skilled in the art to use the Percel et al process as an alternative method to spray coating to coat core particles with the coating agent disclosed in the Japanese patent. Using known alternative technique to achieve the same function would have been obvious to one skilled in the art.

In the response filed with the RCE on May 14, 2004, applicant argues Orthoefer uses a plasticizer to soften the pliable meat analog vegetable protein materials which is different from the use of the plasticizer in the claimed invention. This argument is not persuasive. Orthoefer does not teach to use plasticizer to only soften the protein materials. On column 3 lines 28-30, Orthoefer discloses the edible plasticizer is added to impart flexibility, resiliency and pliability to the vegetable products. While the Orthoefer product is different from the coating product disclosed in the Japanese patent, the use of the plasticizer is for the same purpose. The Japanese patent teaches to add plasticizer for the purpose of improvement of the distensibility of coating film, water resistance. Furthermore, the claims do not have any limitation on the function of the plasticizer. Applicant further argues the main materials which are being treated in Orthoefer, the Japanese patent and the claimed invention are quite different. As pointed out above, the materials are different but the use of plasticizer is essentially for the same purpose.

The argument directed at the Nisperos-Carriedo reference will not be addressed because the reference is no longer used in the rejections.

With respect to the Percel reference, applicant argues even assuming that the coating agent of the present invention could be combined with the coating method of Percel, there is no reasonable expectation for successful coating by using a Percel fluidized-bed chamber. The basis of this argument is not understood. The Japanese reference teaches spray coating. Both spray coating and coating using fluidized bed chamber are known in the art to be used for coating material; it would have been

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obvious to one skilled in the art to use alternative methods to achieve the same function.

Applicant's arguments filed May 14, 2004 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien T Tran whose telephone number is 571-272-1408. The examiner can normally be reached on Tuesday, Wednesday and Friday.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 28, 2004


LIEN TRAN
PRIMARY EXAMINER

Group 1700